UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/533,029	03/22/00	HEARD J	MB1-0010

HM12/1113

KAREN J GUERRERO
MENDEL BIOTECHNOLOGY INC
21375 CABOT BOULEVARD
HAYWARD CA 94545

EXAMINER	
KRUSE,D	
ART UNIT	**PAPER NUMBER**
1638	7

DATE MAILED: 11/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/533,029	HEARD ET AL.	
	Examiner	Art Unit	
	David H Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) 14-16 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I: claims 1-13, drawn to a transformation method and transgenic plant in Paper No. 3, filed 15 September 2000 is acknowledged. The traversal is on the ground(s) that the method of selecting sequences of Group II can be used for the method of transforming plants of Group I. This is not found persuasive because the transformation method of Group I and the sequence selection method of Group II have different method steps and different end products and thus constitute distinct inventions. In addition, it would require unrelated art searches and considerations to examine these distinct inventions.

Applicant's election with traverse of Group h directed to MYB genes (DNA SEQ ID Nos. 31,39,57,61,67,85,87,93,111,120 Encoding Polypeptide SEQ ID Nos. 32,40,58,62,68,86,88,94,112) in Paper No. 6, filed 20 October 2000 is acknowledged. Applicant's traversal is on the grounds that the claims are directed to a particular use of the sequences for plant disease. This is not found persuasive because, as Applicant has claimed transgenic plants comprising nucleotide sequences encoding specific SEQ ID No.'s, it is deemed that each transgenic plant comprising each distinct sequence is a distinct invention. The Patent and Trademark Office recently published its policy for the examination of patent applications that claim large numbers of nucleotide sequences in the Official Gazette, 1192 O.G. 68 (November 19, 1996). Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute

independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. In establishing the new policy, the Commissioner has partially waived the requirements of 37 CFR 1.141et seq. And permit a **reasonable number of such nucleotide sequences** to be claimed in a single application. It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten (10) independent and distinct nucleotide sequences will be examined in a single application.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Applicant is required to amend the elected claims (1-13) to recite the elected Group h sequences, as the instant claims are now drawn to nonelected sequences.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The title should specify transgenic plants comprising polynucleotides encoding transcription factors that confer disease tolerance or resistance.

5. The abstract of the disclosure is objected to because it does not clearly describe the claimed invention. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 101/112

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

In the instant case, transgenic plants comprising nucleotide sequences encoding a polypeptide comprising at least 6 consecutive amino acids of a sequence selected from the group consisting of SEQ ID Nos. 32, 40, 58, 62, 68, 86, 88, 94, and 112, or comprising at least 18 consecutive nucleotides of a sequence selected form the group consisting of SEQ ID Nos. 31, 39, 57, 61, 67, 85, 87, 93, 111, and 120, have not been shown to have a specific and substantial asserted utility. Specifically, the specification of the instant application does not teach the functional role of the putative transcription factors designated as SEQ ID No. 32, 40, 58, 62, 68, 86, 88, 94, or 112,and hence fails

to teach the use of plants transformed with nucleotide sequences encoding said putative transcription factors.

8. Claims 1-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant claims transgenic plants comprising nucleotide sequences encoding a polypeptide comprising at least 6 consecutive amino acids of a sequence selected from the group consisting of SEQ ID Nos. 32, 40, 58, 62, 68, 86, 88, 94, and 112, or comprising at least 18 consecutive nucleotides of a sequence selected form the group consisting of SEQ ID Nos. 31, 39, 57, 61, 67, 85, 87, 93, 111, and 120.

Applicant teaches the identification, using a low stringency hybridization approach, of nucleotide sequences encoding putative transcription factors that hybridize to known transcription factors.

Applicant does not provide definitive evidence that the isolated putative transcription factor polynucleotides encode proteins that actually bind DNA, nor does Applicant teach what promoter region(s) the putative transcription factors regulate, and what physiological processes and/or phenotypes they modulate. In addition, Applicant has not taught how to modify any phenotypic characteristic in transgenic plants comprising nucleotide sequences encoding a polypeptide comprising at least 6 consecutive amino acids of a sequence selected from the group consisting of SEQ ID Nos. 32, 40, 58, 62, 68, 86, 88, 94, and 112, or comprising at least 18 consecutive

nucleotides of a sequence selected form the group consisting of SEQ ID Nos. 31, 39, 57, 61, 67, 85, 87, 93, 111, and 120. Specifically, Applicant has not demonstrated that the putative transcription factors designated as SEQ ID Nos. 32, 40, 58, 62, 68, 86, 88, 94, or 112, do in fact act as transcription factors and how polynucleotides encoding said putative transcription factors can be utilized to produce a desirable phenotype in transgenic plants. In addition, Applicant has not demonstrated that a nucleotide sequence encoding a polypeptide comprising at least 6 consecutive amino acids of SEQ ID Nos. 32, 40, 58, 62, 68, 86, 88, 94, or 112 or comprising at least 18 consecutive nucleotides of a sequence selected form the group consisting of SEQ ID Nos. 31, 39, 57, 61, 67, 85, 87, 93, 111, and 120 would confer upon a transgenic plant disease tolerance or resistance when compared with the same trait of another plant lacking the recombinant polynucleotide.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1, 2, 5, 6, 9, 10, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 2173.05(h). The specific SEQ ID No.'s must be listed. Appropriate correction is required.

11. Claims 2, 4, 5, 6, 9, 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claims 2, 6 and 10, the phrase "conserved domain" is indefinite in light of Applicant's definition on page 6 of the Specification. Applicant describes 5 types of conserved domains thus it is unclear which type is encompassed by the claimed invention. In addition, it is not clear whether the members of the Markush group further define the "conserved domain" at line 2 or the polypeptide at line 1.

At claims 4 and 8, the term "tissue-active" does not state the metes and bounds of the claimed invention as all promoters are presumed to be tissue "active". It is suggested that the term -- tissue-preferred -- or -- tissue-specific -- be used.

At claims 5, 9 and 13, method step "(b)" does not make sense as method step "(a)" already states "transforming a plant". Method step "(b)" is not deemed necessary.

At claims 5 and 13, first line the term "altering" is indefinite because it does not define how tolerance or resistance is altered or what is encompassed in altering tolerance or resistance.

At claim 9, how does "gene" at line 1 relate to "nucleotide sequence" sequence at line 3? The "gene" at line 1 and the "nucleotide sequence" at line 3 appear to be the same. Applicant must better define what "gene" will have altered expression levels.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Klessig *et al*, (U.S. Patent 5,939,601).

Applicant claims a transgenic plant comprising a nucleotide sequence encoding a polypeptide comprising at least 6 consecutive amino acids of a sequence selected from the group consisting of SEQ ID Nos. 32, 40, 58, 62, 68, 86, 88, 94, and 112, a method for altering the disease tolerance or resistance of said transgenic plant, a method for altering the expression levels of at least one gene of said transgenic plant, and a method of altering the disease tolerance or resistance in a transgenic plant comprising at least 18 consecutive nucleotides of a sequence selected form the group consisting of SEQ ID Nos. 31, 39, 57, 61, 67, 85, 87, 93, 111, and 120.

Klessig discloses a transgenic plant comprising a nucleotide sequence that encodes a MYB homologue that has altered disease resistance (Example II, column 17, claim 8). Klessig also discloses a method of transforming a plant with said nucleotide sequence, and discloses that the encoded MYB protein binds to the PR-1a promoter, which is involved in plant disease resistance (claim 4 and Example IE, column 16-17; see last paragraph of example in column 17). Hence, all of the claim limitations were previously disclosed by Klessig.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 09/532591. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant Application and the copending Application are directed to transgenic plants comprising specific MYB encoding nucleotide sequences. The transgenic plants of the instant Application would inherently have the claimed property of the transgenic plants of the copending Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Paula Hutzell can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Amy Nels

AMY J. NELSON, PH.D
PRIMARY EXAMINER

David H. Kruse, Ph.D.
7 November 2000